AUG - 1 2000

K001182

EXHIBIT # 1

510(K) SUMMARY

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

The assigned 5l0(k) number is:_____.

1. **Submitter's Identification:**

Microlife Corporation
9F, 431 Rui Guang Road
Nei Hu,
Taipei 114
Taiwan, Republic of China

Contact:

Mr. Dawkins Liu

Date Summary Prepared: March 20, 2000

2. **Name of the Device:**

Microlife Wrist Watch Blood Pressure Monitor, Model BP-3BU1

3. **Predicate Device Information:**

The Microlife Wrist Watch Blood Pressure Monitor, Model BP-3BU1 is substantially equivalent to the Microlife Automatic Blood Pressure Monitor, Model BP-2BHO, K# 970211.

4. **Device Description:**

The Microlife Wrist Watch Blood Pressure Monitor, Model BP-3BU1 is designed to measure the systolic and diastolic blood pressure and pulse rate of an individual by using a non-invasive technique in which an inflatable cuff is wrapped around the wrist. Our method to define systolic and diastolic pressure is similar to the auscultatory method but uses an electronic capacitive pressure sensor rather than a stethoscope and mercury manometer. The sensor converts tiny alterations in cuff pressure to electrical signals, by analyzing those signals to define the systolic and diastolic blood pressure and calculating pulse rate, which is a well - known technique in the market called the "oscillometric method".

5. **Intended Use:**

The Microlife Wrist Watch Blood Pressure Monitor, Model BP-3BU1 is a device intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the wrist.

6. **Comparison to Predicate Devices:**

Both devices use the well known oscillometric method within the software algorithm to determine the systolic and diastolic blood pressure and pulse rate. A wrist cuff is inflated automatically; deflate rate is controlled but a factory set bleed valve and the deflation pressures are transferred via tubing to a sensor in both units. Each device uses a similar capacitance-type pressure sensor to translate the pressure variations to electrical signals that can be interpreted by an integrating circuit. Once the reading is determined each unit operates a solenoid valve to release the pressure to zero. Our Wrist Watch Blood Pressure Monitor, Model BP-3BU1, differs from the predicate device in the cuff application part.

The interface between the sensor and the microprocessor determines the system's accuracy. For our Wrist Watch Pressure Monitor, Model BP-3BU1, the software is capable of a split slope resolution to improve accuracy over the entire range. Since the range is "split" into the three sections (0 to 100mmHg) (100 to 200mmHg) (200 to 300mmHg) error due to nonlinearity is reduced by the ability to adjunct the slope to best fit the output curve. A nonlinearity of 1% is reduced to 0.33% by splitting the span into three separated linear relations. This way the sensor is matched to the software by using a series of jumpers that profile the slopes to the output of the sensor.

The Microlife Wrist Watch Blood Pressure Monitor, Model BP-3BU1, has field calibration access; this model is initiated by the following steps: (a) Remove one battery from compartment first, (b) When inserting back the battery, press and hold "I/O" key, and don't release it until the battery is inserted well.

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

Testing information demonstrating safety and effectiveness of the Microlife Wrist Watch Blood Pressure Monitor, Model BP-3BU1 in the intended environment of use is supported by testing that was conducted in accordance with the FDA November 1993 Draft "Reviewer Guidance for Premarket Notification Submissions", DCRND, which outlines Electrical, Mechanical and Environmental Performance Requirements.

The following testing was conducted:

a. General Functions Test
b. Reliability Test - Operation Conditions
c. Reliability Test - Drop Testing
d. Reliability Test - Storage
e. Reliability Test - Vibrating Testing
f. EMC Test
g. IEC 60601-1 Safety Test

None of the testing demonstrated any design characteristics that violated the requirements of the Reviewer Guidance or resulted in any safety hazards. It was our conclusion that the Microlife Wrist Watch Blood Pressure Monitor, Model BP-3BU1 tested met all relevant requirements of the aforementioned tests.

8. Discussion of Clinical Tests Performed:

ANSI/AAMI SP10-1992 "National Standard for Electronic or Automated Sphygmomanometers" testing was performed. All relevant sections were addressed and testing conducted. The BP-3BU1 met all relevant requirements of this standard.

9. Conclusions:

We have demonstrated that the Microlife Wrist Watch Blood Pressure Monitor, Model BP-3BU1, is as safe and effective as the predicate, the Microlife Automatic Blood Pressure Monitor, Model BP-2BHO based on electrical, mechanical and environmental testing results as well as the FDA DCRND November 1993 Draft "Reviewer Guidance for Premarket Notification Submissions", and, the ANSI/AAMI Voluntary Standard, SP10-1992 testing results.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 2000

MICROLIFE Corporation
C/O Ms. Susan D. Goldstein-Falk
MDI Consultants, Inc.
55 Northern Blvd.
Suite 200
Great Neck, NY 11021

Re: K001182
Microlife Wrist Watch Blood Pressure Monitor, Model BP-3BU1
Regulatory Class: II (two)
Product Code: DXN
Dated: July 18, 2000
Received: July 20, 2000

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this

response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit B

510(k) Number (if known): K001182

Device Name: Microlife Wrist Watch Blood Pressure Monitor, Model BP-3BU1

Indications For Use:

The Microlife Wrist Watch Blood Pressure Monitor, Model BP-3BU1 is a device intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the wrist.

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K001182

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____ (Per 21 CFR 801.109) OR Over-The-Counter Use ✓ (Optional Format 1-2-96)